Restriction may be required if two or more "independent and distinct" inventions are claimed in one application. 35 U.S.C. § 121; 37 C.F.R. § 1.141. However, Applicants respectfully submit that the main purpose of Rule 141 is to facilitate the search in considering the patentability of the claimed subject matter and to avoid a situation that requires separate and diverse searches to be conducted on claims directed to independent (unrelated) subject matter. Inventions are deemed "independent" if there is no disclosed relationship and/or if the inventions are unconnected in design, operation or effect. See M.P.E.P. § 802.01.

The Patent Office practice as set forth in the MPEP requires that search and examination of the entire application must impose a serious burden on the Examiner before a proper requirement for restriction may be made. MPEP 803, page 800-4, col. 1 (third paragraph in MPEP 803). Thus, the Patent Office encourages the assertion that examination of the entire application may take place where such search and examination can be made without serious burden, even though separate, non-overlapping searches may be required.

The Examiner asserts that the inventions of Groups I and II and IV are unrelated since they are not disclosed as capable of use together and they have different modes of operation, functions or effects. Applicants disagree and cite the specification, page 4, lines 5 –14 as clearly teaching the use of helper plasmid to complement the HBV vector for encapsidation and viral genome replication (Group II) and transducing liver cell using the recombinant HBV vector plasmid and helper plasmid. The allegedly unrelated inventions are thus capable of use together in gene therapy. Applicants respectfully disagree that the asserted reasons have met the conditions for a proper restriction

requirement. The same argument is made for the other invention classification scheme made by the Examiner.

As the Examiner is aware, this invention is directed to gene therapy – which in essence comprises the insertion of a heterologous gene of interest to target cells. The discovery of a recombinant HBV vector, the method of making such vector and the transduction of target cells using said vector are all closely aligned with the same inventive concept. Applicants assert that this restriction requirement is deficient in that a showing has not been made that the involved claims are directed to *independent* inventions. In fact, the relationship among the claimed inventions is such that a reasonable search for the recombinant vector itself would necessarily lead to disclosures, to the extent any exist, of the means for making and utilizing said vector. Thus, it is clear that the present claims are *not* directed to independent inventions, at least because of the common relationship involving gene therapy. This common relationship establishes that the subject matter defined in the present claims is not misjoined.

Accordingly, Applicants respectfully submit that since the examiner has not made a prima-facie showing of a serious burden, it is incumbent upon the Examiner to conduct such a search. Applicants respectfully request that the Examiner reconsider and withdraw this restriction requirement.

Applicants assert that this response is timely and that extensions of time are not required. However, in the event that additional extensions of time are necessary to

prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 50-0622.

Respectfully submitted,

SHANKS & HERBERT

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